(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
9 September 2005 (09.09.2005)

PCT

(10) International Publication Number
WO 2005/083653 A1

(51) International Patent Classification[7]: G09B 23/28

(21) International Application Number: PCT/US2005/004081

(22) International Filing Date: 9 February 2005 (09.02.2005)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/547,396 24 February 2004 (24.02.2004) US

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(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

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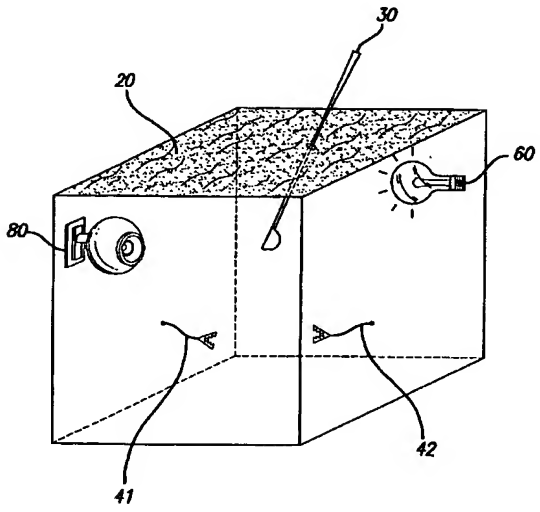
(54) Title: LAPAROSCOPIC SURGERY TRAINING DEVICE WITH ADJUSTABLE INSTRUMENT PLACEMENT



(57) Abstract: Described is a training device used to simulate laparoscopic surgical procedures. The training device container includes at least one penetrable surface constructed of Latex® or a rubber-like material, a gel or a gel-like material, or a similar material that allows for the insertion of laparoscopic instruments at any location without destroying the device. Adjustable clamps or hooks may be included in the device container to secure objects for manipulation with laparoscopic tools. A webcam or digital camera may be included to view and record events inside the training device in real-time. The camera (webcam or digital) may be connected to any suitable electronic device (ie. computer) for real-time visualization of movements within the cavity. The captured real-time movements can be broadcast over the Internet or by other means to remote parties.

WO 2005/083653 A1

Published:
— *with international search report*

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LAPAROSCOPIC SURGERY TRAINING DEVICE WITH ADJUSTABLE INSTRUMENT PLACEMENT

FIELD OF THE INVENTION

The invention relates to the field of training devices for medical procedures. More particularly, the invention relates to a training device that may be used in connection with practicing laparoscopic surgical procedures.

BACKGROUND OF THE INVENTION

Laparoscopic surgery (also referred to as minimally invasive surgery, endoscopic surgery, and videoscopic/telescopic surgery) is a widespread technique that utilizes small incisions or puncture wounds that are just large enough to insert thin tubes with surgical instruments and optical devices. Laparoscopic techniques are used in an astounding array of surgical procedures including gallbladder surgery (cholecystectomies), appendectomies, gastroesophogal-reflux surgery, colorectal surgery, hernia repair, spleen removal, surgical treatment of adrenal tumors, freeing of intraabdominal adhesions, cardiovascular surgery, urologic surgery, gynecologic surgery, and diagnostic laparoscopies. Minimally invasive surgery is rapidly becoming standard treatment around the world, largely because it is less expensive than traditional surgery and significantly less traumatic to the patient. However, because a tremendous level of precision is required in implementing laparoscopic surgical techniques, becoming proficient in performing laparoscopic surgery requires considerable training for physicians.

Recently, advancements in computer graphics and monitors has allowed people to visualize video with clarity and real-time. Furthermore, the web camera (webcam) has allowed users to easily mount and capture live video with ease. Good webcams are now affordable and readily available. The webcam videos can be also be instantly recorded for later viewing. Viewing is not only limited to one's own devices, but through the use of the Internet, can be broadcast to anyone with an Internet connection, globally. Digital cameras can also accomplish similar tasks.

Many medical students, residents in surgery, and physicians wish to learn various laparoscopic techniques, but animal models are not readily accessible and the associated costs of training with them are high. Additionally, the currently available laparoscopic training devices are expensive. Currently used training devices typically employ an endoscope, which is a device that is used to visualize, magnify, and videotape the actions occurring inside a training box.

Endoscopes are quite expensive, and are generally the most significant cost component of these training devices. Furthermore, the endoscopes utilize optical light sources, and television monitors.

Additionally, current training devices for practicing laparoscopic surgical techniques are appreciably limited by the fixed apertures that they include for the insertion of surgical instruments. Currently available training devices generally have a series of pre-cut holes in a rigid surface through which a surgeon can practice laparoscopic procedures by inserting devices; however, the surgeon is not able to insert instruments at locations other than the pre-cut holes. Fixed apertures such as these do not mimic real-life surgical conditions because the surgical instruments cannot be inserted into any location, and the media through which insertion occurs are often rigid or are open holes -- this is markedly dissimilar to human skin. Also, fixed apertures may limit the types of laparoscopic techniques that can be practiced with the training device.

There is therefore a need in the art for a training device that may be used in connection with practicing laparoscopic and other minimally invasive surgical techniques. There is a further need in the art for a training device that is affordable and readily accessible for medical students, residents in surgery, physicians or any individual who wishes to train in laparoscopic procedures. This includes finding an affordable substitute for the expensive endoscope and viewing device. There is a still further need in the art for a training device that is able to simulate real-life conditions encountered during laparoscopic surgery more closely than that which can be achieved with currently available devices.

SUMMARY OF THE INVENTION

The invention is based on a device that may be used for training in connection with various laparoscopic procedures, and methods of using the same. The device is particularly well suited to simulate real-life operating conditions and to assist in training for various operative techniques, as, for example, suturing tissues, cutting off organs and tying knots. The present invention has a number of advantages over currently available training devices currently used in the art as it provides a significantly more versatile training device that can be manufactured at a markedly lower cost.

One embodiment of the present invention thus includes a container with at least one penetrable surface formed of a gel or similar material that can be punctured with a laparoscopic instrument, but which substantially retains its shape when the instrument is removed. The

penetrable surface of the training device may, for example, be constructed of Latex® or a rubber-like material, a gel or a gel-like material, or a similar material.

The training device also includes a webcam, digital camera or other similar real-time video device to monitor the simulated procedure performed inside the container. A webcam or digital camera may be configured inside the container or on its exterior. In those embodiments of the invention wherein the webcam or digital camera is configured on the exterior of the container, the container includes an aperture or transparent surface region through which the camera may create a video of events taking place inside the container. The video, either real-time or captured, may be transmitted to others for viewing using the Internet.

A light source may be included in the container or may be located outside of the container (with an aperture and/or transparent surface region similar to the aperture required for the web or digital camera) to illuminate the container's interior. In addition, grips or clamps configured on adjustable arms may also be included in the container. The clamps may be used, for example, to grasp or hold in place various objects that may be used in connection with a simulated procedure.

In another embodiment of the present invention, a method for laparoscopic surgical training is provided. The method includes any and/or all of the following: mounting one or more objects within a container as described above; inserting a surgical laparoscopic instrument or instruments through any of the at least one penetrable surface such that a first end of the surgical instrument(s) is within the container; performing a simulated laparoscopic procedure by manipulating the surgical instrument(s); and viewing the simulated laparoscopic procedure on a computer or other display apparatus (e.g., a television monitor) via a webcam or digital camera.

Other features and advantages of the invention will become apparent from the following detailed description, taken in conjunction with the accompanying drawings, which illustrate, by way of example, various features of embodiments of the invention.

BRIEF DESCRIPTION OF THE FIGURES

Fig. 1 is a perspective view of a training device in accordance with an embodiment of the present invention.

Fig. 2A is a graphical representation depicting the time required for subjects to complete a first task using a video pelvitrainer system, a dual mirror SIMUVIEW® training system, and a webcam training system in accordance with an embodiment of the present invention.

Fig. 2B is a graphical representation depicting the time required for subjects to complete a second task using a video pelvitrainer system, a dual mirror SIMUVIEW® training system, and a webcam training system in accordance with an embodiment of the present invention.

DETAILED DESCRIPTION

The invention is based on a device that may be used for training in connection with various laparoscopic procedures, and methods of using the same. The device is not limited to use in this particular field of art, however, as it may find application in numerous unrelated fields of art. With respect to laparoscopic surgical training, however, the device is particularly well suited to the simulation of real-life operating conditions and, therefore, to training for various operative techniques; for example, suturing tissues, cutting off organs and tying knots, although still further operative techniques may be performed, as will be readily appreciated by those of skill in the art of laparoscopy. The present invention is useful in the teaching, training and improving of eye-hand coordination, manual dexterity and surgical technique.

In one embodiment, as depicted in Fig. 1, a laparoscopic training device may include a container. It will be readily appreciated by those skilled in the art that the container may be configured in any of a variety of shapes. As illustratively depicted in Fig. 1, the container is roughly a cube, although it may also be, for example, spherical, cylindrical, or may be shaped so as to mimic a particular region of the human body (*e.g.*, the pelvic or abdominal cavity) or to maximize storage and/or shipping efficiency as a commercial product.

Any or all of the sides of the container may independently be configured so as to be fixed or openable. Depending upon the configuration of the container and the overall shape used therefor, one or more sides of the container may be made openable; thereby providing access into the container's interior to enable one to, for instance, set up or remove objects (e.g., foam rubber simulations of human organs) for practicing a surgical technique. Such objects may be mounted and anchored on pads and/or platforms of the same or different material. Alternatively, as illustrated in Fig. 1, an object or objects can be maintained in position by one or more adjustable or malleable grips; two grips **41, 42** are illustratively depicted in Fig. 1, although any number of grips may be included in the container of the invention in still further alternate embodiments thereof.

As depicted in Fig. 1, the container of the invention may include at least one penetrable surface **20**. The penetrable surface **20** is capable of being punctured with a laparoscopic instrument **30**, but it substantially retains its shape when the instrument **30** is removed. The penetrable surface **20** of the training device may, for example, be constructed of Latex® or a

rubber-like material, a gel or a gel-like material, or a similar material; although additional materials that exhibit the desired properties may be used in alternate embodiments of the invention and are considered to be within the ambit thereof, as will readily be appreciated by those of skill in the art.

In the training device illustrated in Fig. 1, a single penetrable surface **20** is included and is configured as the top surface of the training device; however, the container may include multiple penetrable surfaces (not shown). Furthermore, in still additional alternate embodiments of the present invention, the top surface of the container need not be a penetrable surface. Rather, the container may be configured such that the penetrable surface is located on one or more of the sides of the container, or at still another location. This depends, at least in part, on the overall shape selected for the container and the intended use therefor. Furthermore, the gel-like surface can be configured so as to be slidably or otherwise removable from the side of the training device to which it is mated during normal use. As such, the gel-like surface can be readily removed and replaced; particularly when it has already been used repeatedly.

The training device of the invention may further include a web or digital camera **80**. The web or digital camera **80** may be in communication with the Internet, such that operative techniques performed by a device user may be viewed and/or recorded. The web or digital camera **80** may alternatively or additionally be in electronic communication with any suitable electronic device, as will be readily appreciated by those of skill in the art; for example, a digital video recorder, a computer, a local area network, or the like (not shown). The webcam or digital camera may be connected to a portable or desktop computer with software that enables it to operate.

The web or digital camera of the invention enables one to, for example, visualize laparoscopic instrument maneuvers in real-time (e.g., on a television monitor) while the procedure is being performed. This is very similar to the manner in which actual laparoscopic surgery is performed. The video taken by the web or digital camera may alternatively or additionally be broadcast over the Internet or another network or electronic mode of communication for "telementoring" or group discussions. This may be particularly valuable in connection with the invention's use as a teaching tool for students at remote locations. Furthermore, any video may be recorded by conventional systems for later viewing or archiving.

The web or digital camera **80** may be configured inside the container or on its exterior. In those embodiments of the invention wherein the web or digital camera **80** is configured on the exterior of the container, the container includes an aperture or transparent surface region through which the camera **80** may create a video of events taking place inside the container. A light

source 60 may be also included in the container or may be located outside of the container (with an aperture and/or transparent surface region similar to the aperture required for the web or digital camera 80) to illuminate the container's interior.

The objects located within the cavity may also include, simply by way of example, a hook and loop fastener tape set to secure it in a particular location for performing a practice procedure. Any hook and loop fastener set known in the art may be used, as for example, a Velcro® hook and loop fastener set. Other apparatuses for securing, affixing, or removably mounting objects at various locations within the container may be used in alternate embodiments; for instance, snap fittings, adhesive tape, buttons, and the like.

Another embodiment of the invention provides a simulation method for laparoscopic techniques using a training device. The method may be employed in connection with training and/or enhancing the skills of an individual in a laparoscopic procedure. This simulation method includes providing a surgical training device substantially as described above. One or more objects may be included or placed inside the container of the device, and may remain loose or may be affixed thereto or otherwise removably mounted therein. By way of example, the one or more objects may be simulative of components of internal human anatomy. A webcam or digital camera included in the training device may be activated so as to record events occurring inside the container of the training device. A light may be turned on to illuminate an interior of the container of the training device.

The simulation method may further comprise any or all of the following: removably inserting an endoscopic instrument through any site through a penetrable surface configured on the training device such that a first end of the instrument is within the container of the device while a second end of the instrument is outside the container of the device; manipulating the second end of the instrument to effect actuation and/or movement of the first end of the instrument such that an operative procedure is mimicked; viewing maneuvers of laparoscopic instruments on a display via the digital or web camera; and transmitting and/or broadcasting the maneuvers occurring within the container via the Internet.

EXAMPLE

The Example described herein demonstrates one of various uses for the device of the present invention in connection with training for surgical procedures. The device of the present invention has many uses beyond those illustrated herein, however, and the ensuing Example is in no way intended to delineate the extent to which the device of the present invention may find

application with a medical, or indeed any type of procedure.

A training device, substantially as described above, is provided. It includes a webcam, a cardboard box for a container, a desk lamp as a light source, and a home computer in electronic communication with the webcam to record and transmit video of events inside the container across the Internet. This training device was evaluated against two commercially available systems: video PELVITRAINER (Karl Storz) and the dual mirror SIMUVIEW (Simulab). The PELVITRAINER consists of a fiberglass box, a single lens optic laparoscope, a fiberoptic light source, an endoscopic camera, and a video monitor. The SIMUVIEW trainer utilizes two offset, facing mirrors and an uncovered plastic box.

Forty-two participants without prior laparoscopic training were enrolled in the study and asked to execute two tasks: object-transfer (a first task) and pattern-cutting (a second task). Participants were randomly assigned to six groups, with each group representing a different permutation of trainers to be used. The time required for participants to complete each task was recorded, and differences in performance were calculated. Paired *t*-tests, Wilcoxon signed-rank test, and analysis of variance test were performed to analyze the statistical difference on the performance times for all conditions.

Statistical analyses for both tasks evidenced no significant difference for the video and webcam trainers (Figs. 2A and 2B). However, the mirror trainer gave significantly higher outcome values when compared to the video ($p=0.01$ for the first task and $p<0.01$ for the second task) and webcam ($p=0.04$ for the first task and $p<0.01$ for the second task) trainers. An analysis of variance test indicated no overall difference across the orderings ($p=0.36$ for the first task and $p=0.99$ for the second task). However, by the third attempt, the time required to complete both skill tests decreased significantly for all three trainers ($p<0.01$ for both tasks).

In conclusion, the inventive training device offers an inexpensive alternative for learning basic laparoscopic skills for those without prior experience in laparoscopic procedures.

While the description above refers to particular embodiments of the present invention, it should be readily apparent to people of ordinary skill in the art that a number of modifications may be made without departing from the spirit thereof. The accompanying claims are intended to cover such modifications as would fall within the true spirit and scope of the invention. The presently disclosed embodiments are, therefore, to be considered in all respects as illustrative and not restrictive, the scope of the invention being indicated by the appended claims rather than the foregoing description. All changes that come within the meaning of and range of equivalency of the claims are intended to be embraced therein.

WHAT IS CLAIMED IS:

1. A laparoscopic training device, comprising:

a container to house at least one object for simulation of a laparoscopic surgical procedure; and

a penetrable surface configured on said container, said penetrable surface being constructed of a material that substantially retains its shape after being punctured with an instrument and said instrument is removed.

2. The training device of claim 1, further including a webcam or digital camera, said webcam or digital camera being configured either inside said container or outside said container.

3. The training device of claim 2, wherein said webcam or digital camera is configured outside said container, said training device further including a camera transparent surface or a camera aperture to permit said webcam or digital camera to record events taking place inside said container.

4. The training device of claim 1, wherein said penetrable surface is constructed of a material selected from the group consisting of Latex®, a rubber-like material, a gel, a gel-like material, and combinations thereof.

5. The training device of claim 1, further including a light source, said light source being configured either inside said container or outside said container.

6. The training device of claim 5, wherein said light source is configured outside said container, said training device further including a light source transparent surface or a light source aperture to permit said light source to illuminate an interior of said container.

7. The training device of claim 1, said container further including at least one openable side.

8. The training device of claim 1, wherein said container is configured in a shape selected from the group consisting of cubical, spherical, cylindrical, and a shape that mimics a region of the human body.

9. The training device of claim 1, wherein said container further includes at least one grip configured on an adjustable or malleable arm.

10. A laparoscopic training device, comprising:

a container to house at least one object for simulation of a laparoscopic surgical procedure; and

a webcam or digital camera, said webcam or digital camera being configured either inside said container or outside said container.

11. The training device of claim 10, wherein said webcam or digital camera is configured outside said container, said training device further including a camera transparent surface or a camera aperture to permit said webcam or digital camera to record events taking place inside said container.

12. The training device of claim 10, further including a penetrable surface configured on said container, said penetrable surface being constructed of a material that substantially retains its shape after being punctured with an instrument and said instrument is removed.

13. The training device of claim 12, wherein said penetrable surface is constructed of a material selected from the group consisting of Latex®, a rubber-like material, a gel, a gel-like material, and combinations thereof.

14. The training device of claim 10, further including a light source, said light source being configured either inside said container or outside said container.

15. The training device of claim 14, wherein said light source is configured outside said container, said training device further including a light source transparent surface or a light source aperture to permit said light source to illuminate an interior of said container.

16. The training device of claim 10, said container further including at least one openable side.

17. The training device of claim 10, wherein said container is configured in a shape selected from the group consisting of cubical, spherical, cylindrical, and a shape that mimics a region of the human body.

18. The training device of claim 10, wherein said container further includes at least one grip configured on an adjustable or malleable arm.

19. A method of practicing a laparoscopic technique, comprising:

providing a laparoscopic training device, comprising:

a container to house at least one object for simulation of a laparoscopic surgical procedure, and

a webcam or digital camera, said webcam or digital camera being configured either inside said container or outside said container;

activating said webcam or digital camera to record events taking place inside said container; and

performing a laparoscopic procedure with said laparoscopic training device such that a portion of said procedure that takes place inside said container is recorded by said webcam or digital camera.

20. The method of claim 19, wherein said webcam or digital camera is configured outside said container, and said laparoscopic training device further includes a camera transparent surface or a camera aperture to permit said webcam or digital camera to record events taking place inside said container.

21. The method of claim 19, wherein said laparoscopic training device further includes a penetrable surface configured on said container, said penetrable surface being constructed of a material that substantially retains its shape after being punctured with an instrument and said instrument is removed, and wherein performing said laparoscopic procedure with said laparoscopic training device further includes puncturing said penetrable surface with a laparoscopic instrument and removing said instrument therefrom.

22. The method of claim 21, wherein performing said laparoscopic procedure with said laparoscopic training device further includes manipulating at least one object inside said container.

23. The method of claim 21, wherein said penetrable surface is constructed of a material selected from the group consisting of Latex®, a rubber-like material, a gel, a gel-like material, and combinations thereof.

24. The method of claim 19, further including viewing said events taking place inside said container by viewing an output from said webcam or digital camera.

25. The method of claim 24, wherein said viewing said events taking place inside said container is performed in real-time.

26. The method of claim 24, wherein said viewing said events taking place inside said container is performed at a remote location by virtue of said webcam or digital camera being in electronic communication with an electronic device that enables the transmission of said recording across a network.

27. The method of claim 26, wherein said network is selected from the group consisting of a local area network and the Internet.

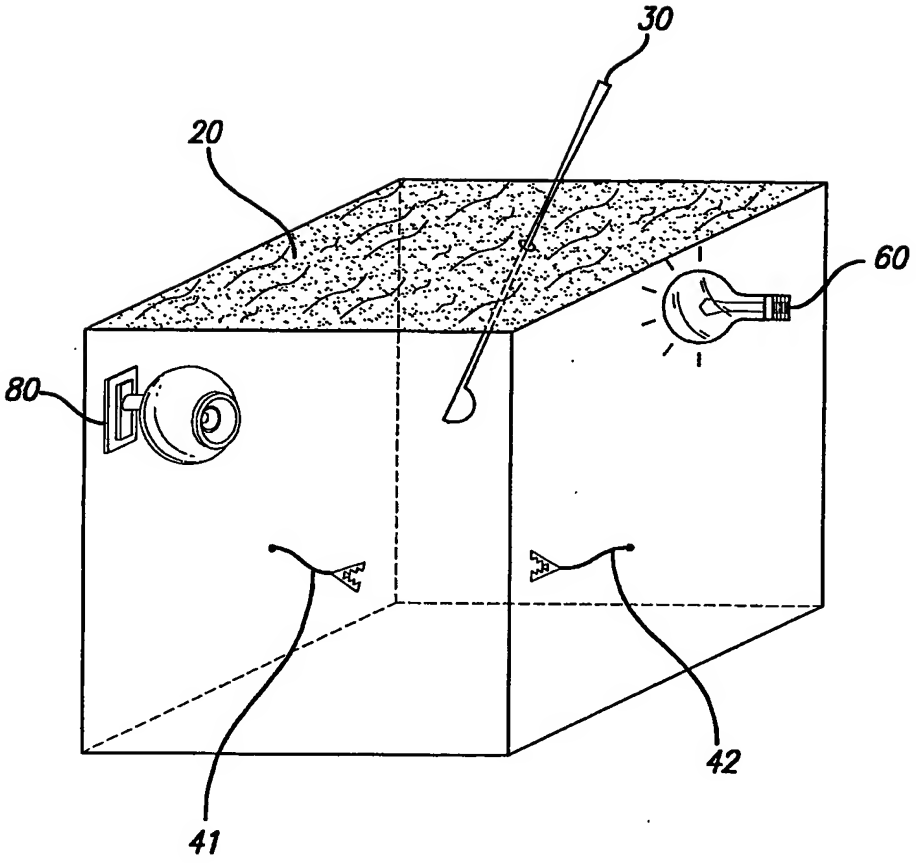
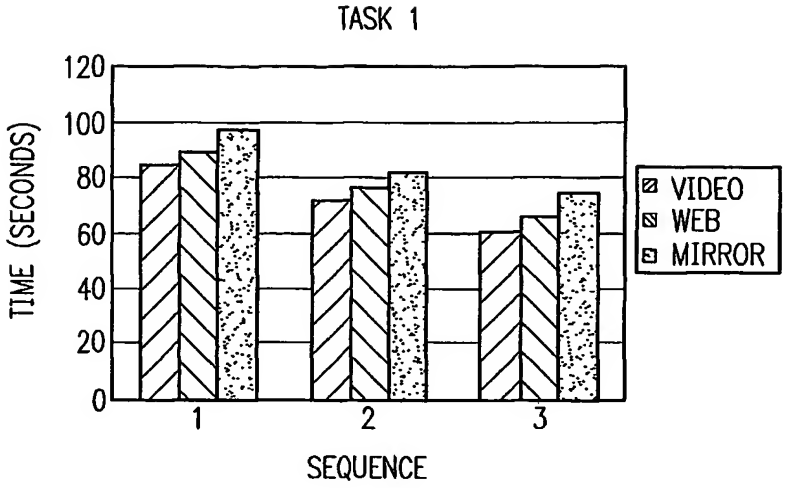


FIG. 1


TASK 1
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20
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1
2
3
SEQUENCE
VIDEO
WEB
MIRROR

FIG. 2A

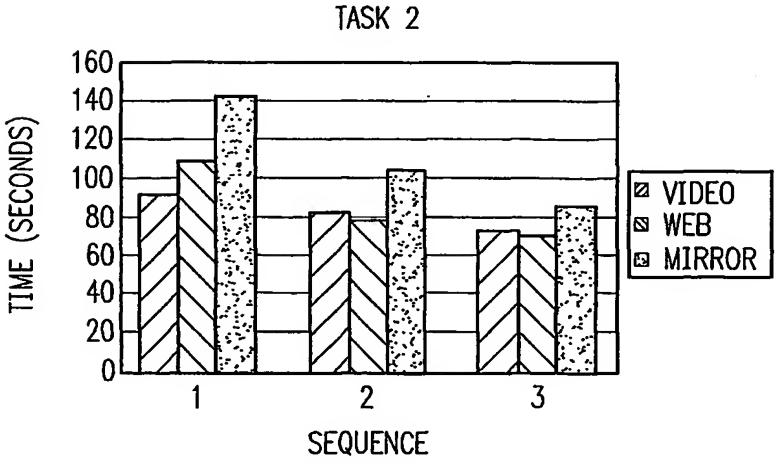
TASK 2
TIME (SECONDS)
160
140
120
100
80
60
40
20
0
1
2
3
SEQUENCE
VIDEO
WEB
MIRROR

FIG. 2B

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US2005/004081

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 G09B23/28

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 G09B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	DE 41 05 892 A1 (PIER, ARNOLD, DIPL.-ING. DR.MED., 5138 HEINSBERG, DE) 27 August 1992 (1992-08-27) column 2, lines 24-56 column 3, lines 50-55	1,4,7-9
Y	column 5, lines 13-18	2,3,5,6, 11-13, 15,20, 21,23

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

* Special categories of cited documents :

'A' document defining the general state of the art which is not considered to be of particular relevance

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'P' document published prior to the international filing date but later than the priority date claimed

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'X' document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

'Y' document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

'&' document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
12 May 2005	10/06/2005

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Beauce, G

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US2005/004081

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6 659 776 B1 (AUMANN ROBERT J ET AL) 9 December 2003 (2003-12-09)	10,14, 16-19, 22,24-27
Y	column 1, lines 34-51; figure 1 column 1, line 60 - column 2, line 7 column 2, lines 22-26 column 2, lines 35-51	2,3,5,6, 11-13, 15,20, 21,23
A	US 5 403 191 A (TUASON ET AL) 4 April 1995 (1995-04-04) column 7, lines 12-27; claim 1; figure 1	1-27

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/US2005/004081

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US 5403191 A	04-04-1995	NONE	